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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,446	01/18/2000	HUGH W. PRICE	7841-89	5954

1059 7590 11/26/2003

BERESKIN AND PARR  
SCOTIA PLAZA  
40 KING STREET WEST-SUITE 4000 BOX 401  
TORONTO, ON M5H 3Y2  
CANADA

EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/402,446

Applicant(s)

PRICE ET AL.15

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23-29, 31-39 and 57-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-29, 31-36, 38 and 39 is/are allowed.
- 6) ☒ Claim(s) 37 and 57-73 is/are rejected.
- 7) ☒ Claim(s) 57-73 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Amendment Entry***

1. The amendment filed September 2, 2003 has been entered. Claims 23, 31-36, 39, 57, 65-70 and 73 have been amended. Therefore, claims 23-29, 31-39 and 57-73 are under consideration in this Office Action.

### ***Specification***

2. The use of the trademarks TWEEN 80<sup>TM</sup> and other reagents has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

### ***Claim Objections***

3. Claims 57-73 are objected to under 37 CFR 1.75(c), as being improper for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 23 is drawn a method of increasing serum half-life by combining an immune globulin. The immune globulin of claim 23 and likewise the dependant claims encompass both monoclonal and polyclonal antibodies; therefore claims 57-73 are not further limiting. Clarification is required to overcome the objection.

***Withdrawal of Rejections***

4. The following rejections have been withdrawn in view of applicants' amendments:
- a) the rejections of claims 23-39 under 35 U.S.C. 112, first paragraph;
  - b) the rejection of claims 23, 26, 31-34 and 36-37 under 35 U.S.C. 102(b) as being anticipated by Alberici et al., WO 94/16728; and
  - c) the rejection of claims 23-34 and 36-38 under 35 U.S.C. 103(a) as being unpatentable over Friesen (CA 1,168,152) in view of de Burgh Bradley et al., (1,303,533).

***Response to Arguments***

5. Applicant's arguments filed September 2, 2003 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. The new matter rejection of claims 57-73 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention is maintained. The rejection was on the grounds that applicants added claims 57-73 drawn to a method for increasing serum half-life of a polyclonal immune globulin, yet the amendment lacks support.

Applicants assert that the specification contains support for the term "polyclonal immune globulin at pages 15 and 17. However, the new matter issue was not directed at how to define a polyclonal immune globulin, but rather that there is no teaching of a method for increasing serum half-life of polyclonal immune globulins. The pages to which applicants' point are drawn to Rh monoclonal antibodies being prepared from polyclonal antibodies or that polyclonal antibodies can be used in standard immunological assays. Applicants have failed to provide support for a

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method for increasing serum half-life regarding using polyclonal immune globulin. There is no support for a method for increasing half-life using polyclonal antibodies wherein the purity and weight percent of the polyclonal immune globulin has been disclosed. Furthermore, the specification fails to provide support for the combination of non-ionic surface-active agents with the polyclonal immune globulin to create a method that increases serum half-life. There is no teaching of the claimed method or method steps that increase serum half-life using a polyclonal antibody and non-ionic surface-active agents. Applicants' arguments still have not pointed to support for the method by page and line number. Therefore, the rejection is maintained because the claims incorporate new matter.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.


7. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 37 is unclear as to how one can administer a lyophilized preparation of immune globulin to an animal. It is also unclear if the preparation must be re-constituted first, or if applicant intends another form of administration. Therefore, clarification is required to overcome the rejection.

*Allowable Subject Matter*

8. Claims 23-29, 31-36 and 38-39 are allowable.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines   
November 18, 2003

  
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